

Case No. 141621-1

**REMARKS**

Claims 1-3 and 5-23 are pending in the present Application. Claims 1 and 19 have been amended, leaving Claims 1 – 3 and 5 - 23 for consideration upon entry of the present Amendment. No new matter has been introduced by these amendments. Reconsideration and allowance of the claims are respectfully requested in view of the above amendments and the following remarks,

**Amended Claims**

Claims 1 and 19 have been amended to contain the term "stain resistant". Support for the term can be found in at least paragraph [0015] on page 3 of the specification as filed.

**Claim Rejections Under 35 U.S.C. § 103(a)**

Claims 1 – 3 and 5 – 18 stand rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over U.S. Patent No. 6,183,248 to Chishti et al. (Chishti) in view of U.S. Patent Application No. 20020082360 to Conn et al. (Conn). (Office Action dated 07/14/05, page 2) Applicants respectfully traverse this rejection.

In making the rejection, the Examiner states "Chishti does not teach a specific polyester. Conn teaches a shell (sheet) comprising polycarbonate and cycloaliphatic polyester. It would have been obvious to one having ordinary skill in the art at the time the invention was made to specify the polyester as a cycloaliphatic polyester in order to provide a shell that is free of blisters in view of Conn." (Office Action dated 07/14/05, page 2)

For an obviousness rejection to be proper, the Examiner must meet the burden of establishing a *prima facie* case of obviousness, i.e., that all elements of the invention are disclosed in the prior art; that the prior art relied upon, coupled with knowledge generally available in the art at the time of the invention, contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combined references; and that the proposed modification of the prior art had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made.

Case No. 141621-1

*In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *In Re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); *Amgen v. Chugai Pharmaceuticals Co.*, 927 U.S.P.Q.2d, 1016, 1023 (Fed. Cir. 1996).

The present application is directed to and claims an appliance for use in an oral cavity, wherein the appliance comprises a stain resistant polymeric shell that has cavities designed to receive teeth, and wherein the shell comprises a thermoplastic polymeric mixture that comprises a polycarbonate and a cycloaliphatic polyester.

Chishti teaches a polymeric overlay or shell having a teeth-receiving cavity formed therein. (see Abstract) Chishti teaches that the shell comprises at least one layer of polymeric material. (see Claim 1) Chishti discloses that the layer of polymeric material can be a shape memory polymer, methacrylate containing polymers, acrylate containing polymers, thermoplastic polymers, cross-linked thermoplastic polymers, thermoplastic polymer blends, cross-linked thermoplastic polymer blends, thermoplastic elastomer polymers, and thermoset polymers. (see Claim 6) Chishti further teaches that a layer of the shell can comprise a crosslinked polyester/polycarbonate blend in the Table in Col. 10. (see heading to the Table in Col. 10)

While Chishti teaches that the shell can comprise thermoplastic polymer blends and thermoset polymers including a crosslinked polyester/polycarbonate blend, Chishti does not specifically teach a shell that comprises a thermoplastic polymeric mixture that comprises a polycarbonate and a cycloaliphatic polyester as presently claimed. Chishti does not teach a polycarbonate-cycloaliphatic polyester blend that is stain resistant. For this reason at least, Chishti does not teach all elements of the claimed invention.

Conn teaches films formed from a blend of polycarbonate and a copolyester. (see Abstract) Conn teaches that the copolyester component of the blend at least one, or more of poly(1,4-cyclohexylene- dimethylene terephthalate) (PCT), poly(1,4-cyclohexylenedimethylene naphthalenedicarboxylate) (PCN), poly(1,4-cyclohexylenedimethylene 1,4- cyclohexanedicarboxylate) (PCC) copolymers, or mixtures

Case No. 141621-1

thereof. (see Page 1, paragraph [0011]) However, the blends of polycarbonate and copolyester disclosed by Conn undergo yellowing. (see page 3, paragraph [0029]) Conn also teaches that in order to prevent yellowing, a phosphite stabilizer must be added to the blend. (see page 3, paragraph [0029])

While Conn teaches cycloaliphatic polyesters, one of ordinary skill in the art would not seek to combine Chishti with Conn, since Conn teaches away from Chishti. In addition, Conn teaches away from the present invention as well.

In the first instance, Conn in not teaching stain resistant polycarbonate-cycloaliphatic polyester blends does not teach all elements of the claimed invention. Conn therefore does not make up for the deficiency of Chishti. In addition, as noted above, Conn teaches away from the claimed invention. The claimed invention is directed to a dental appliance that is stain resistant. Conn in teaching that its resin undergoes a change to yellow coloration would therefore not be usable as a dental appliance. In this regard, the courts have stated that "a *prima facie case of obviousness may also be rebutted by showing that the art, in any material respect, teaches away from the claimed invention.*" *In re Geisler*, 116 F.3d 1465, 1471, 43 USPQ2d 1362, 1366 (Fed. Cir. 1997).

With respect to the combination of Chishti with Conn, Chishti teaches that crosslinked polycarbonate polyester blends are used in a dental appliance system. (see Abstract) Conn teaches that the polycarbonate-cycloaliphatic polyester blends are thermoplastics. Evidence of this can be seen from the fact that the blends are thermoformable. (see Examples; see also paragraph [0043] on page 4) In the first instance, one of ordinary skill in the art upon reading Chishti and noting the use of crosslinked (i.e., thermosetting) resins would not seek to combine it with Conn's thermoplastic resins.

In addition, as noted above, Conn teaches that its blends undergo a yellow coloration, which is suppressed by the addition of a phosphite stabilizer. One of ordinary skill in the art desirous of making a dental appliance system for stabilizing teeth would prefer to use a material that does not undergo yellowing, as this would reduce the aesthetic appeal of the

Case No. 141621-1

appliance. For this reason at least, one of ordinary skill in the art upon reading Conn would be demotivated from combining it with Chishti. In addition, one of ordinary skill in the art would not seek to add phosphite stabilizer to a resin that is being placed in the mouth without proper medical testing and FDA approval. For this reason at least, the artisan skilled in the art would desist from combining Chishti with Conn in the manner undertaken by the Examiner.

In addition, comparative testing documented in the present application shows unexpectedly superior results for the claimed composition. For example, Table 5 on page 32 shows that the presently claimed invention has a yellowness index b\* of 1.51 and 1.52 (see Sample 4 and 5) while comparative samples show a yellowness index b\* of 1.80 to 2.47 (see Comparative Samples 1 through 3). Quite clearly the claimed polycarbonate-polycster blends do not undergo yellowing as compared with the blends disclosed by Conn and this is unexpected. In this regard, the courts have stated that “[A]n applicant can rebut a prima facie case of obviousness by presenting comparative test data showing that the claimed invention possesses unexpectedly improved properties or properties that the prior art does not have. *In re Dillon*, 919 F.2d 688, 692-93, 16 U.S.P.Q.2d 1987, 1901 (Fed. Cir. 1990).

In summary, the combination of Chishti with Conn does not teach all elements of the claimed invention, there is no motivation to combine Chishti with Conn, and the claimed invention displays unexpectedly superior results. For these reasons at least, the Examiner has not made a prima facie case of obviousness over Chishti in view of Conn. Applicants respectfully request a withdrawal of the obviousness rejection over Chishti in view of Conn.

Claims 19 and 20 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,975,893 to Chishti et al (hereinafter Chishti '893) in view of Chishti and Conn. (Office Action dated 07/14/05, page 3)

Claim 19 as presently amended is directed to a method for maintaining or repositioning teeth in the oral cavity comprising placing an appliance in a patient's mouth, wherein the appliance comprises a stain resistant polymeric shell having cavities designed to receive teeth, and wherein the appliance that comprises a polymeric mixture, and further

Case No. 141621-1

wherein the polymeric shell has cavities designed to receive teeth, that comprises a polycarbonate and a cycloaliphatic polyester.

Chishti '893 teaches a system for repositioning teeth comprises a plurality of individual appliances. (see Abstract) Chishti '893 teaches that the appliances are configured to be placed successively on the patient's teeth and to incrementally reposition the teeth from an initial tooth arrangement, through a plurality of intermediate tooth arrangements, and to a final tooth arrangement. (see Abstract) While Chishti '893 describes that the appliances comprise a polymeric shell (see Claim 12) and further discloses that the polymeric shell is preferably formed from a thin sheet of a suitable elastomeric polymeric, such as Tru-Tain, commercially available from Tru-Tain Plastics, Rochester, Minn. 55902, Chishti '893 does not teach a shell that comprises a polymer mixture that comprises a polycarbonate and a cycloaliphatic polyester. Chishti '893 further does not teach that the shell is stain resistant.

As noted above, neither Chishti nor Conn teaches a stain resistant shell. Hence Chishti '893 does not make up for the deficiency of Chishti or Conn and the combination of Chishti '893 with Chishti and Conn does not teach all elements of the claimed invention.

In addition, as noted above, Conn teaches away from Chishti. Conn in teaching a polycarbonate-cycloaliphatic polyester blend that undergoes yellowing teaches away from Chishti '893 as well, since Chishti '893 is also directed to dental appliances whose aesthetic appeal would be compromised by any yellowing.

In addition, as noted above, Conn in disclosing yellowing teaches away from the claimed invention which is directed to a stain resistant shell that comprises the polymeric blend of polycarbonate and cycloaliphatic polyester.

In summary, since the combination of Chishti '893 in view of Chishti and Conn does not teach all elements of the claimed invention and since Conn teaches away from Chishti '893 as well as Chishti, the Examiner has not made a prima facie case of obviousness over Chishti '893 in view of Chishti and Conn. Applicants therefore respectfully request a withdrawal of the obviousness rejection over Chishti '893 in view of Chishti and Conn.

Case No. 141621-1

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and allowance are requested.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 50-3621.

Respectfully submitted,

CANTOR COLBURN LLP

By   
David E. Rodrigues  
Registration No. 50,604

Date: October 11, 2005  
CANTOR COLBURN LLP  
55 Griffin Road South  
Bloomfield, CT 06002  
Telephone (860) 286-2929  
Facsimile (860) 286-0115  
Customer No.: 23413